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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,548	07/18/2005	Siegfried Ansorge	013183.00041	8485

26712 7590 09/14/2007
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EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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09/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,548

Applicant(s)

ANSORGE ET AL.

Examiner

Abdel A. Mohamed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENT TO THE PRELIMINARY AMENDMENT AND THE STATUS OF THE CLAIMS

The preliminary amendment filed 09/14/04 is acknowledged, entered and considered. In view of Applicant's request claims 1-10, 12, 15, 17 and 20-22 have been amended and claims 23-42 have been added. Claims 1-42 are active and pending in the application.

ELECTION/RESTRICTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 16-25 and 32-42, drawn to a method for the preparation of pharmaceutical preparations for the inhibition of the proliferation (DNA synthesis) of human sebaceous cells by utilizing the inhibitors of dipeptidyl peptidase IV (DP IV) and inhibitors of enzymes having a similar substrate specificity (DP IV-analogous enzyme activity) and/or of inhibitors of alanyl aminopeptidase (aminopeptidase N, APN) and inhibitors of enzymes having a similar substrate specificity (APN-analogous enzyme activity).

Group II, claim(s) 6-15 and 26-31, drawn to a method for inhibition of the proliferation (DNA systems) of human sebaceous cells by utilizing the inhibitors of

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dipeptidyl peptidase IV (DP IV) and inhibitors of enzymes having a similar substrate specificity (DP IV-analogous enzyme activity) and/or of inhibitors of alanyl aminopeptidase (aminopeptidase N, APN) and inhibitors of enzymes having a similar substrate specificity (APN-analogous enzyme activity).

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inhibitions of the proliferations of DNA synthesis by using DP IV and/or APN and their preparation thereof is directed to a special technical feature, defined as a contribution over the art as admittedly acknowledged in the instant disclosure of page 2, paragraph 2, lines 7-12 and on page 4, paragraph 2, lines 9 and 10 as taught by Schon et al (Biomed. Biochim, Acta 1985, 2:K9-K15), and Neubert et al German patent No. DD 296075A5, respectively. Group I (claims 1-5, 16-25 and 32-42) is directed to a method for the preparation of pharmaceutical formulation for the inhibition of the proliferation (DNA synthesis) of human sebaceous cells and Group II (claims 6-15 and 26-31) is directed to a method of inhibition of the proliferation (DNA synthesis) of human sebaceous cells.

Thus, the methods of Group I and II using the same compounds (i.e., DPIV and/or APN) as recited above do not correspond to the same technical features and are not connected in design, operation or effect because they differ in method steps, parameters and reagents used, and as such, the methods as grouped are independent and distinct, each from the other because they represent different technical features and

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different inventive endeavors. Further, the pharmaceutical preparations of Group I (claims 1-5, 16-25 and 32-42) could be used as diagnostic formulations instead of a method for inhibition of the proliferation of human sebaceous cells as claimed in Group II (claims 6-15 and 26-31). Hence, the compounds used in different methods have different structures, functions and different effects. Thus, the Groups require different patent and literature search and a reference teaching a method for the preparation of pharmaceutical formulation will not teach a method for inhibition the proliferation and *vice versa*. Therefore, Groups I and II do not share the same technical features, the inventions do not relate to the same inventive concept.

ELECTION OF SPECIES

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species I is drawn to inhibitors of DP IV and/or APN listed in claims 2-4 and 17-19 (Group I); claims 7-9 and 12-14 (Group II).

Whichever groups are elected, the above claims listed as Species I will be examined with the elected groups.

Species II is drawn to utilizing of DP IV inhibitor for a prevention and therapy for a) benign follicular hyperproliferation conditions, b) SAHA syndrome, and c) malignant

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follicular hyperproliferation conditions listed in claims 5 and 23 -25 (Group I); claims 10, 15 and 26-31 (Group II).

Whichever groups are elected the above claims listed as Species II (a-c), will be examined with the elected groups.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species I and II are related as independent pharmaceutical formulations comprising various DP IV and/or APN inhibitors containing different physiologically active amines and their salts as active ingredients while Species II is specifically directed to use of the above formulations of Species I for prevention and therapy of various diseases and/or conditions as recited in claims 5 and 23-25 (Group I); claims 10, 15 and 26-31(Group II).

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The various inhibitors of DP IV and/or APN of Species I and utilizing DP IV inhibitor for a prevention and therapy of various diseases and hyperproliferation conditions of Species II do not correspond to the same technical feature and are not connected in design, operation or effect because they differ in structure and formulation, and as such, the inhibitors of enzymes as grouped are different from each other because they represent different technical features and different inventive endeavors. Hence, DP IV and/or APN inhibitors formulations have different structures, functions and different effects. Thus, the species require different patent and literature search and a reference teaching the various inhibitors and/or APN (Species I) will not teach the utilization of DP IV inhibitors for a prevention and therapy of various diseases and hyperproliferation conditions (Species II) and *vice versa*. Therefore, Species I and II do not share the same technical features, the inventions do not relate to a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

CONCLUSION AND FUTURE CORRESPONDANCE

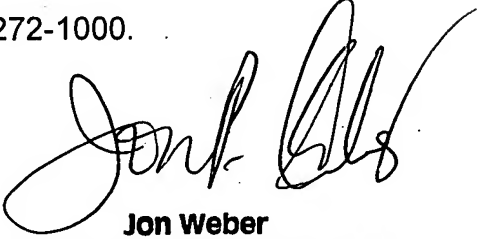
Claims 1-42 are subject to restriction and/or species election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 Mohamed/AAM
September 10, 2007


Jon Weber
Supervisory Patent Examiner